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10/552,034

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Bo Mattiasson

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MCDERMOTT WILL & EMERY LLP  
600 13TH STREET, N.W.  
WASHINGTON, DC 20005-3096

EXAMINER

ZALASKY, KATHERINE M

ART UNIT

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1797

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/552,034	<b>Applicant(s)</b> MATTIASSON ET AL.	
	<b>Examiner</b> KATHERINE ZALASKY	<b>Art Unit</b> 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 28 May 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 10-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 19-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Claim Status*

1. **Claims 1-22**, as amended 28 May 2010, are currently pending. **Claims 10-18** are withdrawn.

### *Claim Rejections - 35 USC § 103*

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. **Claims 1-9 and 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bojanic et al. (US 5,417,923) in view of Provonchee et al. (US 5,277,915).**

Regarding **claims 1, 8 and 19-22**, Bojanic et al. discloses a method for the chromatographic separation of substances contained in a liquid sample and a separation device for use in a method for the chromatographic separation of substances contained in a liquid sample (abstract) comprising:

- providing a one piece separation tray having a spaced array of discrete identical upstanding chambers each exhibiting an open upper end and an open lower end and a separation medium placed in at least part of each upstanding chamber (Figure 1, Figure 3, C3/L18-22, C4/L8-23)
- applying a liquid sample to said open upper end of at least one of said upstanding chambers, then applying an eluting liquid to said open upper end of is said at least one of said upstanding chambers; and collecting at least one product fraction flowing out from the open lower end of said at least one of said upstanding chambers (C6/L60-68, C7/L43-62)

While the reference does disclose that the separation medium in the chromatography chamber is preferably a monolithic plug which is closely received by the cylindrical bore

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(C6/L39-46), Bojanic et al. does not disclose that the monolith is a compressible macroporous gel having in its liquid-swollen, non-compressed state a cross-sectional area which is 2-15%, 4-12%, and 5-10% larger than the cross-sectional area of the upstanding chamber in which it is placed is used as said separation medium and is in face-to-face contact with the wall of the respective chamber in its liquid-swollen state.

Provonchee et al. discloses a compressible monolithic gel with pores in the range of 0.1 microns to 1000 microns which is suitable for chromatography applications (abstract, C2/L21-26, L32-38). The gel is stronger than conventional gels and is able to be manipulated into various shapes and forms (C2/L52-60). In its compressed/dewatered state, the mass of the gel is 10% to 90% of the mass of the original swollen/watered gel (C2/L32-38). Furthermore, depending on the desired chromatography application, the gel may be derivatized with various functional groups (C5/L45-50).

It would have been obvious to one having ordinary skill in the art at the time of the invention to use the compressible macroporous gel which can be manipulated into various shapes and derivatized with various functional groups for the monolithic stationary phase of Bojanic et al., as taught by Provonchee et al., since doing so provides the separation assay with a mechanically strong and flexible gel which may be modified depending on the desired use. Additionally, it would have been obvious to one having ordinary skill in the art to obtain the details regarding the monolithic stationary phase which are missing from the Bojanic reference by performing a literature search, or by reviewing other known documents in the art, such as Provonchee et al.

Additionally, it has been well documented in the art that monolithic chromatography media can have problems with seepage along their length, next to the column wall (as evidenced by US 2005/0155933 and citations contained therein, [0003], [0004] and also

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US6136187, C2/L35-49). This problem is caused by shrinkage of the monolith material as it polymerizes. Typically, the problem is addressed by using heat-shrinkable tubing on the outside of the monolithic rod to tightly address the column or other forms of cladding, such as an epoxy filler. Provonchee offers an alternative solution which allows for a conventional column structure, with the option to increase or decrease the gel size by adjusting the water content of the gel. This presents an additional solution to a well documented problem in the art. This alternative solution would be apparent to one skilled in the art and one would be able to appreciate the benefits of a solution which does not require additional column structure or manufacturing steps.

Regarding **claims 2 and 9**, modified Bojanic discloses all of the claim limitations as set forth above. Additionally, Provonchee et al. discloses the method and separation device wherein the monolith of a compressible macroporous gel is a cryogel that has been obtained by polymerizing a solution of one or more monomers selected from the group consisting of: N-substituted and non-substituted (meth)acrylamides, N-alkyl substituted N-vinylamides, hydroxyalkyl (meth)acrylates, vinylacetate, alkylethers of vinyl alcohol, styrene and ring-substituted styrene derivatives, vinyl monomers, (meth)acrylic acid and salts thereof, silicic acid, and monomers capable of forming polymers via polycondensation under freezing at a temperature below the solvent crystallization point, at which solvent in the system is partially frozen with the dissolved substances concentrated in the non-frozen fraction of solvent to the formation of a cryogel (C4/L64-68, polyacrylamides, C4/L47-60).

Regarding **claim 3**, modified Bojanic discloses all of the claim limitations as set forth above. Additionally, Provonchee et al. discloses the method wherein the monolith of a compressible macroporous gel is a cryogel that has been obtained by cooling an aqueous solution of polyvinyl alcohol or at least one gel forming polysaccharide selected from the group

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consisting of agarose, agar, carrageenans, starch and cellulose and their respective derivatives or a mixture of said polysaccharides to a temperature, at which the solvent in the system is partially frozen with the dissolved substances concentrated in the non-frozen fraction of the solvent to the formation of a cryogel, said cooling being carried out, when necessary, in the presence of at least one chaotropic agent in said aqueous solution in order to prevent gel formation before the polymer solution is frozen (C5/L29-35, polysaccharides preferred, C4/L47-60, Example 5, C10/L12-30).

Regarding **claim 4**, modified Bojanic discloses all of the claim limitations as set forth above. Additionally, while Provonchee et al. discloses two separate embodiments, one in which a cross-linked polyacrylamide polymer is used to form the gel and one in which a polysaccharide is used to form the gel, the reference does not disclose that both may be used in the same embodiment and that they become cross-linked. However, it would have been obvious to one having skill in the art to combine the two embodiments such that a combination of cross-linked polymers and polysaccharides are used in the gel formation since doing so amounts to nothing more than the combination of known prior art elements. Additionally, it was known in the art at the time of the invention to form hydrogels from a combination of cross-linked polymers and polysaccharides (as evidenced by Fujii et al., abstract, C7/L11-21).

Regarding **claim 5**, modified Bojanic discloses all of the claim limitations as set forth above. Additionally, Provonchee et al. discloses the method wherein the polymer and polysaccharide, respectively, has become modified by introducing a member selected from the group consisting of ligands, charged groups and hydrophobic groups thereinto (C5/L45-50).

Regarding **claim 6**, modified Bojanic discloses all of the claim limitations as set forth above. Additionally, while Provonchee et al. discloses that the formed gel may be in the form of a sheet and that because of its strength, it may be easily manipulated into different shapes

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(C2/L51-60, C6/L45-49), the reference does not disclose that the monolith has been formed by rolling or folding a sheet of a cryogel. However, many methods of placing a monolith into a column are known in the art. For example, Provonchee et al. discloses that a plug of the monolithic material can be inserted into a column (C10/L45-55). Additionally, it is known that monolithic sheets can be rolled into a spiral cylinder or folded into a planar stack for use in a reaction chamber (as evidenced by Bae et al., US 20020169077, abstract). Therefore, it would have been obvious to one having ordinary skill in the art to choose rolling or folding a monolithic sheet since doing so amounts to nothing more than a choice from a finite number of identified, predictable solutions for ways to place a monolithic material into a column. Additionally, one would have a reasonable expectation of success since the gel material is disclosed as being strong and easily manipulated into different forms.

Regarding **claim 7**, modified Bojanic discloses all of the claim limitations as set forth above. Additionally, Provonchee et al. discloses the method wherein the monolith of a compressible macroporous gel has been produced by a method selected from the group consisting of: gel formation in double emulsion systems, freeze-drying of a polymer solution, leaching of a particulate material used as a porogen from a preformed polymer monolith, use of gas bubbles as a porogen when gel formation proceeds in foam, and aggregation of polymer particles or fibers (non-woven materials) (C2/L27-41, C4/L47-60).

### ***Response to Arguments***

4. Applicant's arguments filed 28 May 2010 have been fully considered but they are not persuasive.

5. The Applicant has argued that the Provonchee reference does not teach a monolithic macroporous gel, but rather a "gel-in-matrix". The Applicant's point is understood; Provonchee includes a monolithic hydrogel within a reticulated open-cell foam support. The preamble of

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**claim 1** is written with the term "comprising", meaning that it is not limited to the features recited in the body of the claim. In this case, the reference may disclose a matrix in addition to the monolithic gel; however, this additional structure is not prohibited by the claim language. Therefore, this argument is not persuasive.

6. The Applicant has argued that there is no rationale for incorporating a monolithic macroporous gel in Bojanic's construction because the reference already includes frits. Applicant has argued that the use of a monolithic media would be redundant in view of the frits and therefore, one of ordinary skill in the art would not be motivated to make the combination. This argument is not persuasive because Bojanic already proposes a continuous chromatographic media in the wells (C6/L34-51), with the alternative to the cylindrical plug being powder, slurry or other forms (C6/L57-59).

7. The Applicant has argued that the citations given with respect to claim 3 are improper as they do not read on the claim language. The Applicant has argued that the instant claims require generation of the macroporous structures by freezing polymer solution without any additional matrix. The language of claim 3 states: "...wherein the monolith of a compressible macroporous gel is a cryogel that has been obtained by cooling an aqueous solution of polyvinyl alcohol or at least one gel forming polysaccharide...or a mixture of said polysaccharides to a temperature, at which the solvent in the system is partially frozen with the dissolved substances concentrated in the non-frozen fraction of the solvent to the formation of a cryogel...". There is no language in the claim which prohibits an additional matrix from being present. C5/L29-35 of the reference was cited because the claim contains details of the polysaccharide material, this citation contains details of the polysaccharide material used in the reference. C4/L47-60 contain a reference to the freezing of the gel. C10/L12-30 contain an example with details of the freezing process.



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***Conclusion***

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHERINE ZALASKY whose telephone number is (571) 270-7064. The examiner can normally be reached on 7:30am - 6:00pm Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim can be reached on (571)272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Krishnan S Menon/  
Primary Examiner, Art Unit 1797

/KZ/  
14 August 2010